DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 27, 2015

Covidien
Celso Duran
Product Associate, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K142929
Trade/Device Name: LigaSure™ Blunt Tip Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 25, 2014
Received: November 26, 2014

Dear Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
LigaSure™ Blunt Tip Sealer/Divider

Indications for Use *(Describe)*
The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialities as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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COVIDIEN

510(k) Summary

Date summary prepared: 1/27/2015

510(k) Submitter/Holder

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Contact

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Name of Device

Trade Name:	LigaSure™ Blunt Tip Sealer/Divider
Catalog Numbers:	LF1623, LF1644
Common Name:	Bipolar Vessel Sealing Device
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI)

Predicate Device

Trade Name:	LigaSure™ Blunt Tip Laparoscopic Sealer/Divider
Common Name:	Bipolar Vessel Sealing Device
Catalog Number:	LF1637
510(k) Number:	K130744 (cleared 4/17/2013), K141153 (cleared 8/14/2014)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall

No reference devices were used in this submission.

Device Description

The LigaSure™ Blunt Tip Sealer/Divider (LF1623, LF1644) devices are sterile (EtO), single-use, hand held bipolar vessel sealing devices designed for use with Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during open and minimally invasive general surgical procedures (as indicated) using radio frequency (RF) energy. A hand actuated lever allows the user to open or close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position during vessel sealing and cutting. The proposed devices do not contain software.

Indications for Use

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialities as

urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Comparison of Technological Characteristics with the Predicate Device
The application of radio frequency (RF) energy is the principle for both the subject and predicate devices. A seal is created by application of RF energy to structures (vascular and lymphatics) interposed between the jaws of the instrument. A blade within the instrument is user actuated to divide tissue after the seal is created. At a high level, the subject and predicate devices are based on the following same technological elements:

- Bilateral jaws – used to reach target structures (vascular and lymphatics)
- Lever –incorporates a latch mechanism to hold the jaws in the closed position
- Activation button – allows RF energy to be activated by the user
- Cutting trigger – allows user to divide (cut) sealed structures

The only differences between the subject and predicate devices are the length of the shaft.

Performance Data
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the LigaSure™ Blunt Tip Sealer/Divider devices was conducted in accordance with International Standard ISO 10993-1 “Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process”, as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemolysis

The patient-contacting materials are: stainless steel, ceramic; and polymers including ETFE, polycarbonate, polyamide, polyester, polypthalamide, ABS, and thermoplastic elastomer.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing and EMC testing were conducted on the LigaSure™ Blunt Tip Sealer/Divider devices. The system complies with relevant portions of the IEC 60601-1, IEC 60601-2-2, and IEC 60601-2-18 standards for electrical safety and IEC 60601-1-2 standard for EMC.

Mechanical / Functional Testing

Mechanical, electrical, and functional testing was carried out to verify that the devices with the new shaft lengths perform as expected.

- Jaw force
- Jaw gap
- Device resistance, capacitance, and inductance
- Knife deployment force

- Lever latching/unlatching/opening force

***Ex-vivo* Vessel Burst Pressure**

Ex-vivo burst pressure testing of excised fresh porcine renal, pulmonary arteries, and lymphatics was conducted on both the subject and predicate devices to demonstrate bipolar electrosurgical vessel sealing performance.

Thermal Profile

Bench thermal profile testing using porcine tissue was conducted to evaluate the thermal profile of the jaw and shaft of the subject device in comparison to the predicate.

Acute Animal Study

In the animal study conducted, one female pig underwent various procedures to assess acute sealing performance and lateral thermal damage by the subject and predicate devices. Hemostasis rates met the predefined acceptance criteria.

The thermal safety of the new LigaSure™ Blunt Tip Sealer/Divider devices was evaluated by macroscopic and histological evaluation of the tissue that was sealed and divided. These studies demonstrated that the subject devices are as safe and effective as the predicate device.

Chronic Animal Study

Because of similarity to the previously cleared design, the chronic animal study results reported in K130744 are valid for these devices.

Human Factors and Usability

The usability engineering process applied to these products was in compliance with the requirements of IEC 62366:2007 “Medical devices – Application of usability engineering to medical devices”, as recognized by FDA. The process included analysis of user needs and potential use errors. This was followed by testing to demonstrate that representative users can use the instruments safely and correctly.

Clinical Studies

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Summary

Based on the preclinical performance as documented in the performance testing, the LigaSure™ Blunt Tip Sealer/Divider devices were found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The subject devices have the same indications for use as the legally marketed predicate device. The design changes made to introduce the two new device lengths do not raise new kinds of safety and effectiveness questions. Verification and validation data support the substantial equivalence of the modified LigaSure™ Blunt Tip Sealer/Divider devices to the legally marketed predicate device.